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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/516,818

12/07/2004

Junzo Tanaka

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01/23/2009

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EXAMINER

NAFF, DAVID M

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1657

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/516,818	<b>Applicant(s)</b> TANAKA ET AL.	
	<b>Examiner</b> David M. Naff	<b>Art Unit</b> 1657	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 9-11 and 14-17 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-11 and 14-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

An amendment of 10/29/08 amended claims 9, 14, 15 and 17, and canceled claim 13.

Claims examined on the merits are 9-11 and 14-17, which are all claims in the application.

#### 5 *Claim Objections*

Claim 17 is objected to because of the following informalities: the claim is claiming the scaffold of claim 9, however claim 9 is drawn to a composite material. The claim should be dependent on claim 11. Appropriate correction is required.

#### *Claim Rejections - 35 USC § 112*

10 The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15 Claims 15 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is unclear by not claiming a complete method containing all steps needed to produce a composite as required by claim 9. For example, in addition to alternatively soaking, the method would require a step of providing a polymeric material selected from a group as  
20 required in claim 9, and would require the step of alternatively soaking to produce the polymeric material containing the gradient of calcium phosphate.

In claim 17, "the composition gradient" does not have clear antecedent basis since "composition gradient" has been removed from claim 9 by amendment.

#### *Response to Arguments*

25 In regard to claim 15, the amendment urges that the polymeric material recited in claim 9 is already in claim 9, and claim 15 is dependent on claim 9. However, the polymeric material in

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claim 9 is the polymeric material of the composite material that is a product of the method of claim 15. Claim 15 being dependent on claim 9 does not obviate 15 being a complete method. Claim 15 is a method for producing the composite material according to claim 9, and the method must recite all steps needed to produce this composite that would be required if claim 15 is not  
5 dependent on claim 9. Claim 9 cannot supply steps and/or components required in the method since claim 15 is dependent on claim 9 only for producing a composite as required by claim 9, and is not dependent on claim 9 for components and/or steps needed to perform the method of making the composite.

***Claim Rejections - 35 USC § 103***

10           The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

15           (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20           This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any  
evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

25           Claims 9-11 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mattern et al (6,969,523) or Yannas et al (4,947,840) in view of Akashi et al (6,387,414) and Sherwood et al (6,454,811), and if necessary in further view of Taguchi et al (Biomaterials).

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The claims are drawn to a composite material containing a gradient of calcium phosphate in a biodegradable polymeric material selected from collagen, glycosaminoglycan and a composite of collagen and glycosaminoglycan produced by alternatively soaking one side of the material in a calcium ion-containing solution and the other side in a phosphate ion-containing  
5 solution.

Mattern et al (col 1, lines 11-30 and col 3, lines 50-67) and Yannas et al (paragraph bridging cols 1 and 2) disclose scaffolds formed of cross-linked collagen and glycosaminoglycan.

Akashi et al disclose preparing a hydroxyapatite composite by alternatively soaking a  
10 surface of a matrix in a calcium ion-containing solution and in a phosphate ion-containing solution. Matrices that can be used include collagen and a mucopolysaccharide such as hyaluronic acid (col 4, lines 15-17). The composite has a composition similar to bone and is useful as an artificial tissue such as artificial bone, or as medical materials (col 1, lines 6-12).

Sherwood et al disclose (col 4, lines 13-26 and 40-45) forming a gradient of calcium  
15 phosphate in a material such as collagen (col 8, line 50) to provide a composite implantable device for regeneration of bone.

Taguchi et al disclose preparing an apatite coating on hydrophilic polymer-grafted poly(ethylene) films by alternate soaking of the film in a calcium ion-containing solution and phosphate ion-containing solution. The resultant composite may be used as a hard tissue  
20 substitute and as a soft tissue adhesive.

It would have been obvious to provide hydroxyapatite in the cross-linked collagen/glycosaminoglycan scaffold of Mattern et al or Yannas et al by alternatively soaking the scaffold in a calcium ion-containing solution and a phosphate ion-containing solution as suggested by Akashi et al to provide a composite for use as artificial tissue such as artificial

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bone, and as suggested by Sherwood et al to make an implantable composite for bone regeneration. Hydroxyapatite is a calcium phosphate compound disclosed in the present specification (page 5, line 22) that can be the calcium phosphate of the claims. Using alternative soaking as disclosed by Akashi et al only on one side of the scaffold of Mattern et al or Yannas et al would have been obvious when hydroxyapatite is desired at only one side, and subjecting one side to the alternative soaking will inherently provide a gradient of calcium phosphate as claimed. Moreover, Sherwood et al would have suggested a gradient.

Components of claim 11 would have been obvious since the components and their functions are known, and it would have been obvious to provide the components in a scaffold to obtain their expected functions. Providing cells as required by claim 14 would have been obvious to obtain the function of the cells to generate tissue. The scaffold of Mattern et al or Yannas et al is inherently porous as required by claim 16. If needed, Taguchi et al would have further suggested using alternate soaking as claimed to provide calcium phosphate in the scaffold of Mattern et al or Yannas et al.

***Claim Rejections - 35 USC § 103***

Claims 9, 15 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akashi et al.

The invention and Akashi et al are described above.

When preparing the hydroxyapatite composite of Akashi et al by alternatively soaking a surface of a matrix in a calcium ion-containing solution and in a phosphate ion-containing solution, it would have been obvious to use collagen as the matrix as suggested by Akashi et al disclosing that the matrix can be collagen. A gradient as required by the present claims will inherently result.

***Claim Rejections - 35 USC § 103***

Claims 10, 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akashi et al in view of Mattern et al or Yannas et al.

Claim 10 requires the polymeric material to be a crosslinked product of  
5 glycosaminoglycan and collagen.

Mattern et al and Yannas et al are described above.

It would have been obvious to replace the collagen of Akashi et al with the cross-linked collagen/glycosaminoglycan suggested by Mattern et al or Yannas et al to obtain the function of glycosaminoglycan in addition to collagen. Components of claims 11 and 13 would have been  
10 obvious since the components and their functions are known, and it would have been obvious to provide the components in a scaffold to obtain their expected functions. Providing cells as required by claim 14 would have been obvious to obtain the function of the cells to generate tissue.

***Response to Arguments***

15 The amendment urges that Akashi et al do not produce a gradient since the entire matrix is alternatively soaked. However, soaking the entire matrix will not prevent forming a gradient since the gradient can extend from the entire surface of the matrix towards the center of the matrix. Alternatively soaking the entire surface of the matrix will inherently subject one side to the soaking when multiple sides are present. Soaking one side does not exclude soaking other  
20 sides when more than one side is present. The claims do not require the polymeric material to have more than one side and limit the soaking to only one side so that the one side has the ability to induce bone formation due to the action of calcium phosphate and the other side not soaked functions as a scaffold for soft tissue. It is granted that Mattern et al and Yannas et al

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do not form a gradient. However, the formation of a gradient will be formed when alternatively soaking as disclosed by Akashi et al and Taguschi et al.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as  
5 set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on  
10 the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner  
15 should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M. Naff/  
Primary Examiner, Art Unit 1657

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DMN  
1/19/09